



Poseida Therapeutics Presents Preliminary Results from Phase 1 Trial of P-PSMA-101 at the 6th Annual CAR-TCR Summit

August 31, 2021

Encouraging data confirming activity in a solid tumor indication presented on first nine patients at low dose cohorts in ongoing autologous CAR-T trial in metastatic castrate-resistant prostate cancer
Three patients showed a greater than 50% decline in prostate-specific antigen (PSA) and concordant PSMA-PET imaging results, including one patient at lowest dose with evidence of complete tumor elimination
Favorable safety profile with modest overall rates of CRS and no neurotoxicity observed
Company to host webcast today to further review results at 11:00am ET

SAN DIEGO, Aug. 31, 2021 /PRNewswire/ -- Poseida Therapeutics, Inc. (Nasdaq: PSTX), a clinical-stage biopharmaceutical company utilizing proprietary genetic engineering platform technologies to create cell and gene therapeutics with the capacity to cure, today announced preliminary results from its Phase 1 clinical trial of P-PSMA-101, the Company's solid tumor autologous CAR-T product candidate to treat patients with metastatic castrate-resistant prostate cancer (mCRPC). These data will be presented at the 6th Annual CAR-TCR Summit virtual meeting at 10:00am ET today in a presentation entitled, "P-PSMA-101 is a High-Tscm Autologous CAR-T Targeting PSMA Producing Exceptionally Deep and Durable Responses in Castration-Resistant Metastatic Prostate Cancer."

"We are excited about the preliminary data from our Phase 1 trial of P-PSMA-101, which provides further evidence of the effectiveness of our CAR-T platform for solid tumor cancers," said Eric Ostertag, M.D., Ph.D., Chief Executive Officer of Poseida, who will present at the CAR-TCR Summit. "To date, other CAR-T therapeutics have not had much success outside of hematologic malignancies. The deep and durable responses in our trial demonstrate that CAR-T products have the potential to work well against solid tumors, even at low doses, when using the appropriate technology platform."

Efficacy:

As of the cutoff date, the study had enrolled a total of nine patients with mCRPC: five patients at Dose A who each received a single treatment of 0.25X10E6 cells/kg (an average of about 20M cells), and four patients at Dose B, who each received a single treatment of 0.75X10E6 cells/kg (an average of about 60M cells). All patients received a lymphodepletion regimen consisting of 30 mg/m2 fludarabine + 300 mg/m2 cyclophosphamide. Patients were heavily pre-treated, having received an average of six prior lines of therapy with a median time since diagnosis of 6.4 years.

Key findings included:

- Five patients dosed showed measurable declines in PSA levels
- Three patients treated showed a greater than 50% decline in PSA levels and had concordant improvements in PSMA-PET imaging
- One patient demonstrated evidence of complete tumor elimination and remains in a durable response of greater than five months at the time of this presentation

"This innovative Poseida PSMA-directed CAR T cell platform has demonstrated a robust anti-tumor response in patients with metastatic castration resistant prostate cancer," commented Susan F. Slovin, M.D., Ph.D., Associate Vice Chair of Academic Administration at Memorial Sloan Kettering Cancer Center and investigator on the trial. "This is the first time that I have seen such impressive responses with an immunotherapy product. The responses of my patients in the trial are far beyond my expectations."

Safety and Tolerability:

P-PSMA-101 demonstrated a favorable safety and tolerability profile. After a previously reported case of Macrophage Activation Syndrome (MAS) exacerbated by patient non-compliance, only three cases of possible Cytokine Release Syndrome (CRS) were observed, which were all low grade (1/2) and were managed well with early treatment. No cases of neurotoxicity (CRES/ICANS) were observed as of the cutoff date.

The Phase 1 trial is an open label, multi-center, 3+3 dose-escalating study designed to assess the safety of P-PSMA-101 in up to 40 adult subjects with mCRPC. The primary objectives of this study are to determine the safety, efficacy, and maximum tolerated dose of P-PSMA-101. Additional information about the study is available at www.clinicaltrials.gov using identifier: NCT04249947.

"We believe the key to success in solid tumors is a product with a high percentage of desirable stem cell memory T cells (Tscm)," said Matthew Spear, M.D., Chief Medical Officer of Poseida. "In this study, we have demonstrated that a high-percentage Tscm CAR-T product can home to the bone marrow and, in at least one case, completely eliminate tumor. This bone marrow homing property may be particularly important for bone avid diseases such as prostate adenocarcinoma. Importantly, the favorable tolerability associated with our Tscm CAR-T products has carried over to prostate cancer where we have so far seen manageable cytokine release syndrome and no neurotoxicity."

Company-Hosted Conference Call and Webcast Information

Poseida's management team will host a conference call and webcast today, August 31, 2021 at 11:00am ET. The dial-in conference call numbers for domestic and international callers are (866) 939-3921 and (678) 302-3550, respectively. The conference ID number for the call is 50220147. Participants may access the live webcast and the accompanying presentation materials on Poseida's website at www.poseida.com in the Investors section under Events and Presentations. An archived replay of the webcast will be available for 30 days following the event.

Additional CAR-TCR Summit Highlights

Presentation: "Developing CAR-T Cells for Multiple Myeloma: From Autologous to Allogeneic"

Session Date/Time: Wednesday, September 1, 2021, 4:00pm ET

Presenter: Matthew Spear, M.D., CMO, Poseida Therapeutics

This presentation will outline Phase 1 and 2 development of the Company's lead autologous P-BCMA-101 CAR-T therapy and insights that were used to develop a fully allogeneic version, P-BCMA-ALLO1 that is expected to enter the clinic soon. The presentation will be part of the afternoon session on the Clinical Management Track.

Presentation: "Advancing Nonviral Manufacturing for Multi-Product Allogeneic T-Cell Therapies"

Session Date/Time: Wednesday, September 1, 2021, 4:30pm ET

Presenter: Devon Shedlock, Ph.D., SVP Research & Development, Poseida Therapeutics

This presentation will discuss how Poseida's piggyBac[®] DNA Delivery System, Cas-CLOVER[™] Site-specific Gene Editing System and Booster Molecule are used to manufacture multi-product, fully allogeneic T-cell therapies. The Company will also discuss how efficient multiplexed Cas-CLOVER gene editing exhibits low to no off-target editing or translocations as determined by next-generation sequencing, and how the Company's Booster Molecule helps to protect against the "allo tax," maintaining a favorable high-stem cell memory T cell (Tscm) product and enabling up to hundreds of doses in a single manufacturing run. This presentation will be part of the afternoon session on the Manufacturing Track.

Presentation: "Developing 'Off-the-Shelf' CAR-T Cells for Bone Marrow Transplant Conditioning"

Session Date/Time: Thursday, September 2, 2021, 9:00am ET

Presenter: Nina Timberlake, Ph.D., Associate Director, Research (Gene Therapy), Poseida Therapeutics

This presentation will discuss leveraging the piggyBac DNA Delivery System and Cas-CLOVER Site-specific Gene Editing System to generate off-the-shelf fully allogeneic CAR-T cells to specifically target hematopoietic cells in the bone marrow. This potential therapeutic could be used as a non-myeloablative conditioning regimen for hematopoietic stem cell transplant or as a therapeutic for the treatment of acute myeloid leukemia (AML). The presentation will occur as part of the conference's Focus Day, "CAR-TCR Beyond Oncology: Fundamental Biology & Mechanisms of Action Beyond Oncology."

The full presentations at the CAR-TCR Summit will be made available on Poseida's website at their respective session times.

About Poseida Therapeutics, Inc.

Poseida Therapeutics is a clinical-stage biopharmaceutical company dedicated to utilizing our proprietary genetic engineering platform technologies to create next generation cell and gene therapeutics with the capacity to cure. We have discovered and are developing a broad portfolio of product candidates in a variety of indications based on our core proprietary platforms, including our non-viral piggyBac DNA Delivery System, Cas-CLOVER Site-specific Gene Editing System and nanoparticle- and AAV-based gene delivery technologies. Our core platform technologies have utility, either alone or in combination, across many cell and gene therapeutic modalities and enable us to engineer our wholly-owned portfolio of product candidates that are designed to overcome the primary limitations of current generation cell and gene therapeutics. To learn more, visit www.poseida.com to connect with us on [Twitter](#) and [LinkedIn](#).

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the potential benefits of Poseida's technology platforms and product candidates, Poseida's plans and strategy with respect to developing its technologies and product candidates, and anticipated timelines and milestones with respect to Poseida's development programs. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. These forward-looking statements are based upon Poseida's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks and uncertainties associated with development and regulatory approval of novel product candidates in the biopharmaceutical industry and the other risks described in Poseida's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Poseida undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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